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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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4

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/520,130

Applicant(s)

Arathoon et al

Examiner

Minh-Tam Davis

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 7, 2000
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

1. ☐ Notice of Opposition (see 37 CFR 1.102)
2. ☒ Notice of Unpublished Examination (see 37 CFR 1.141)
3. ☐ Information Disclosure Statement (see PTO 1449, Paper No. 3)
4. ☒ *Sequence rule compliance notice*

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DETAILED ACTION

SEQUENCE RULE

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821-25 for the reasons set forth on the attached Notice to Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant is required to comply with the sequences rules at the time of the election of the following restriction. See attached papers for sequence rule compliance.

APPLICANT IS GIVEN A ONE MONTH EXTENDABLE PERIOD WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

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I. Claims 1-3, 8-11, 21, 22, 24-27, 30, drawn to a method for preparing a multispecific antibody, wherein the multimerization domain is altered to comprise a free thiol, classified in class 435, subclass 69.1.

II. Claims 1, 2, 4-11, 21-23, 25-27, 30, drawn to a method for preparing a multispecific antibody, wherein the multimerization domain is altered to comprise a protuberance and a cavity, classified in class 435, subclass 69.1.

III. Claims 12-15, 18, 31, 33, drawn to a multispecific antibody, wherein the multimerization domain is altered to comprise a free thiol, classified in class 530, subclass 387.3.

IV. Claims 12-14, 16-18, 31, 33, drawn to a multispecific antibody, wherein the multimerization domain is altered to comprise a protuberance and a cavity, classified in class 530, subclass 387.3.

V. Claims 19, 20, 32, drawn to a host cell comprising nucleic acid encoding a multispecific antibody, wherein the multimerization domain is altered to comprise a free thiol, classified in class 435, subclass 252.3.

VI. Claims 19, 20, 32, drawn to a host cell comprising nucleic acid encoding a multispecific antibody, wherein the multimerization domain is altered to comprise a protuberance and a cavity, classified in class 435, subclass 252.3.

wherein the multimerization domain is altered to comprise a free thiol, classified in class 435, subclass 7.1.

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VIII. Claim 29, drawn to a method for measuring the formation of a multispecific antibody, wherein the multimerization domain is altered to comprise a protuberance and a cavity, classified in class 435, subclass 7.1.

In addition, upon the election of any of groups I-VIII, further election of the following patentably distinct species of the claimed invention is required:

The constant domain is a CH3 domain or is from a human IgG.

Upon the election of any of groups I-VIII, further election of the following patentably distinct species of the claimed invention is required:

Anti-Ob-R/anti-HER3 or anti-Mp1/anti-HER3.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions (I-II, VII-VIII) and (III-VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h)). In this instant case, a DNA sequence could be used for the detection of similar DNA or RNA sequences, for making an expression vector, and for producing its encoded protein; and an antibody could be used for immunoassay, for purification of its

The products of groups III-VI are patentably distinct, because they are drawn to entirely different biochemicals or cells, wherein alteration by adding a free thiol would produce a

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multimerization domain having different structures than a multimerization domain having a protuberance and a cavity.

The methods of groups I-II, VII-VIII are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

The species constant domain are distinct because they are structurally distinct.

The species anti-Ob-R/anti-HER3 or anti-Mpl/anti-HER3 are distinct because they are structurally distinct.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art as shown by their different classification, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a)

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tess Canute, can be reached on (703) 308-3995. The fax phone number for this Group is

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0016.


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Minh-Tam B. Davis

June 20/2001


SUSAN UNGAR, PH.D.
PRIMARY EXAMINER